

REMARKS

This amendment is in response to the Office Action, dated August 18, 2006 ("Office Action"), and in light of the telephone Interviews on January 4, 2007 ("Interview I"), and January 11, 2007 ("Interview II") with Examiners Melenie McCormick and Christopher Tate. Applicant thanks Examiners McCormick and Tate for their assistance. In the Office Action, claims 1-3, 5-13, 19-30, 32 and 33 were pending; claims 1-3, 5-13, 19-30, 32 and 33 were rejected; and claims 8-9 were objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all the limitations of the base claim and any intervening claims. Claims 1-3, 5-13, and 19-33 have been canceled (claims 4 and 14-18 having previously been canceled); and new claims 34-62 have been added by virtue of the present amendment. No new matter has been added. Allowance and reconsideration of the application in view of Applicant's amendment and the ensuing remarks are respectfully requested. Applicant reserves the right to pursue other aspects of the present invention in later filed applications.

During Interview I, Examiners indicated that composition claims that include the limitations of previously presented claims 8 and 9 will be in condition for allowance. Examiner also suggested additional language in previously presented claim 8 (currently claim 43) to further clarify the claim. Further, methods of making and methods of using the compositions that include the aforementioned limitations will also be in condition for allowance. Examiners indicated that while claims to a method of using the soluble fiber from fruit of the *Musa* spp. to treat inflammatory bowel disease in a subject "*in need thereof*" may overcome the inherency issue in the prior art of record, the claims have not been examined for treating inflammatory bowel disease in a subject "*in need thereof*" and thus a Request for Continued Examination will need to be filed to pursue the claims.

During Interview II, Examiners reiterated that a method of using the compositions that include the aforementioned limitations to treat inflammatory bowel disease would be in condition for allowance. With respect to a claim for a method of using a soluble fiber from the fruit of the *Musa* spp. (that is not limited by the aforementioned limitations)

to treat inflammatory bowel disease in a subject, Examiners raised, for the first time, possible enablement issues relating to the different Musa species. Nonetheless, Examiners indicated that an amendment to previously presented claim 24 (currently claim 34) defining the soluble fiber as being derived from plantains would be entered as it has been enabled by the specification. With respect the inherency issue set forth in the Office Action, Examiners indicated that an amendment to indicate that the method is for treating a subject *with inflammatory bowel disease* would address the inherency issue and place the claim in condition for allowance.

Claim 34 has been added and is similar to previously presented claim 24, but recites that the soluble fiber is derived from a *plantain* and that the method is for treating inflammatory bowel disease in a subject *with inflammatory bowel disease*.

Claim 35 has been added and is similar to previously presented claim 25, but recites that a *plantain* is the source of the soluble fiber.

Claim 36 has been added and is similar to previously presented claim 26, but clarifies that a *plantain* is the source of the soluble fiber.

Claims 37-42 have been added and are similar to previously presented claims 27-30 and 32-33, respectively.

Claim 43 has been added and is similar to previously presented claim 8, incorporates the limitations of previously presented claim 1, and includes additional language that further clarifies the claim.

Claim 44 has been added and is similar to previously presented claim 3 but recites that "heating the solution comprises boiling the solution." Support for this amendment may be found throughout the specification; for example, on pages 6 and 7.

Claim 45 has been added and is similar to previously presented claim 10.

Claims 46-47 have been added and are similar to previously presented claims 12-13.

Claim 48 has been added and is similar to previously presented claim 9, incorporates the limitations of previously presented claim 1, and includes additional language that further clarifies the claim, including a recitation that the soluble fiber is substantially starch free.

Claim 49 has been added and is similar to previously presented claim 11 but corrects for a minor grammatical error and for proper dependent claim form.

Claim 50 has been added and is similar to previously presented claim 19, and includes language to reflect that the soluble fiber is obtained by a method that includes the limitations of claims 43 or 48.

Claim 51 has been added and is similar to previously presented claim 20.

Claim 52 has been added and is similar to previously presented claim 21 and includes language to clarify the antecedent basis and to recite that the soluble fiber is substantially starch free.

Claims 53-54 have been added and are similar previously presented claims 22-23.

Claim 55 has been added and recites a method of producing the product of claim 43.

Claim 56 has been added and recites a method of producing the product of claim 48.

Claim 57 has been added and recites a method of using the product of claims 43 or 48. Support for this amendment may be found throughout the specification and originally filed claim 24.

Claims 58-62 have been added and are similar to dependent claims 38-42.

In the Office Action, Examiner maintained her rejection of claims 1-3, 5-7, 19-30 and 32-33 under 35 U.S.C. §102(b) as anticipated or alternatively, under 35 U.S.C. §103(a) as being obvious over Fagbemi (Plant Foods for Human Nutrition 54:261-269, 1999).

Examiner found that Fagbemi's composition "appears to be identical to the presently claimed fiber composition." Further, Examiner found that Fagbemi teaches that its flour can be incorporated into food and beverage products. Examiner asserted that "even if the claimed...composition is not identical to the referenced...composition[,] the differences...are considered to be so slight that the referenced...composition is likely to inherently possess the same characteristics of the claimed...composition [unless applicant provides objective evidence showing otherwise]." Examiner found that

the "inevitable ingestion of the food product taught by Fagbemi would intrinsically treat Inflammatory Bowel Disease with respect to preventing Inflammatory Bowel Disease," because the claims read on treating Inflammatory Bowel Disease in a subject so as to prevent or reduce the risk of the disease.

Examiner further found that the composition taught by Fagbemi, being boiled, would remove an amount of starch to be substantially starch free. Examiner also found that ripened plantains would have less starch due to the conversion of starch to simple sugars in the ripening process. Examiner also found that while Fagbemi did not disclose that its composition contained soluble fiber, boiled plantains contain soluble fiber as disclosed by Tanya *et al.*

With respect to canceled claims 1-3, 5-7, 19-30 and 32-33, these rejections are rendered moot. Notwithstanding the canceled claims, Applicant respectfully traverses this rejection and provides the following comments with respect to new claims 34-62.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. MPEP §2131 (citing *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987)). Furthermore, a reference cannot be relied upon as anticipatory to the extent that the scope of its disclosure does not reasonably suggest those aspects relied upon in the rejection. See *Merck & Co. v. Biocraft Laboratories*, 874 F.2d 804, 10USPQ2d 1843 (Fed. Cir.), *cert. denied*, 493 U.S. 975 (1989); MPEP §2123.

Additionally, three basic criteria must be met to establish a *prima facie* case of obviousness: (1) "there must be some suggestion or motivation...to combine reference teachings," (2) "there must be a reasonable expectation of success," and (3) *the prior art references "must teach or suggest all the claim limitations."* MPEP §2142 (emphasis added). A reconstruction based on hindsight reasoning may be proper if it takes account only knowledge which was within the level of ordinary skill in the art at the time of the claimed invention was made and does not include knowledge gleaned from applicant's disclosure. See *In re McLaughlin*, 443 F.2d 1392, 1395 (CCPA 1971).

New and unobvious uses of a known compound, based on an unknown property of the compound, may be patentable. See MPEP 2112.02 (citing *In re Hack*, 245 F.2d 246, 248 (CCPA 1957)).

When making a rejection based on inherency, an Examiner must provide rationale or evidence tending to show inherency. "The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic." See MPEP §2112(IV) (citing *In re Rijkkaert*, 9 F.3d 1531, 1534 (Fed. Cir. 1993) (emphasis in original). Further, "to establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.'" *Id.* (citing *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999)).

Applicant respectfully submits that Fagbemi does not anticipate Applicant's invention because Fagbemi does not teach the composition, the method of producing the composition, or the method of using the composition to treat IBD as required by Applicant's claims.

The Compositions Are Novel and Nonobvious

Examiner found that claims 8 and 9 would be allowable if rewritten in independent format with all the limitations of their base claims and any intervening claims. New claim 43 has been added and includes the limitations of previously presented claim 8 and the base claim (previously presented claim 1). New claim 48 has been added and includes the limitations of previously presented claim 9 and the base claim (previously presented claim 1). New claim 50 has been added and is similar to previously presented claim 19, and includes the limitations of previously presented claims 1, 8 and 9 (currently claims 43 and 48). Accordingly, Applicant respectfully submits that claims 43, 48, and 50 and claims 44-47, 49 and 51-54, which depend from claims 43, 48 or 50, are allowable.

The Methods of Treating IBD Are Novel and Nonobvious

"In general, a limitation or the entire invention is inherent and in the public domain if it is the 'natural result flowing from' the explicit disclosure of the prior art." *Perricone v. Medicis*, 432 F.3d 1368, 1377 (Fed. Cir. 2005), (citing *Schering Corp. v. Geneva Pharms.*, 339 F.3d 1373, 1379 (Fed. Cir. 2003)). However, in *Perricone*, the Court found that the prior art did not "disclose topical application to skin sunburn" and "skin sunburn" is not analogous to skin surfaces generally and thus "the disclosed use of [the prior art compound], i.e., topical application [to skin], does not suggest application of [the prior art compound] to skin sunburn." *Id.* at 1378-79. The Court found that Perricone's method of *treating* sunburn by applying its product to sunburned skin was not inherently anticipated by the prior art. The prior art was a cream that contained a variety of ingredients in a range of concentrations, including those in Perricone's product and ranges claimed by Perricone. The Court focused on the whether the prior art disclosed the use of Perricone's claimed product on sunburned skin, and found that the prior art did not disclose this limitation.

New claim 34 provides for a method for treating Inflammatory Bowel Disease in a subject "*with inflammatory bowel disease*" and the method comprises administering the composition to a *subject with inflammatory bowel disease*. Fagbemi does not teach or suggest a method of treating IBD with a soluble fibre derived from fruit of *Musa* spp. Fagbemi does not inherently anticipate a method of treating IBD in a *subject with inflammatory bowel disease* with a soluble fibre derived from fruit of *Musa* spp. Even assuming for a moment that Applicant's composition is not new, which Applicant in no way concedes, a new and unobvious use of the composition based on an unknown property is still patentable. Applicant has found that the soluble fiber is effective in treating IBD. This finding was a discovery of an unknown property and thus the method of treating IBD using the soluble fiber is a new and unobvious use of the soluble fiber. Examiner asserted that IBD is inherently prevented or the risk of the IBD is inherently reduced through the "inevitable ingestion of the food product taught by Fagbemi." However, Fagbemi did not disclose every limitation of claim 34 and the claims that depend therefrom. Particularly, Fagbemi did not disclose the limitation of administering the composition to a subject with IBD. Similar to *Perricone*, administering the

composition to a subject with IBD is not disclosed by the alleged prior art use of Fagbemi's composition, and is not the same as administering the composition to a subject in general. Thus, claim 34 and claims that depend therefrom are not anticipated by Fagbemi. Applicant further notes that Fagbemi does not render obvious claim 34 or the claims that depend therefrom because Fagbemi makes no mention of the use of soluble fiber derived from fruit of the *Musa* spp., and more particularly from a plaintain to treat IBD.

In light of the foregoing remarks, Applicant respectfully requests reconsideration and withdrawal of these rejections under 35 U.S.C. §102(b) and §103(a).

Methods of Producing and Using the Compositions
Are Novel and Nonobvious

Applicants respectfully draw Examiner's attention to the following:

"Where the application as originally filed discloses the product and the process for making and/or using the product, and only claims directed to the product are presented for examination, applicant may present claims directed to the process of making and/or using the allowable product by way of an amendment...Amendments submitted after final rejection are governed by 37 CFR 1.116. When all claims to the elected product are in condition for allowance, all process claims eligible for rejoinder (see MPEP §821.04) must be considered for patentability." MPEP §821.04(b). (Emphasis in original.)

New claims 55 and 56 recite a method of making the compositions of claim 43 and 48, respectively, and contain all the limitations of claim 43 and 48, respectively. As such, Applicant respectfully submits that claims 55 and 56 are also allowable.

New claims 57-62 recite methods of using the compositions of claims 43 and 48 to treat inflammatory bowel disease. As such applicant respectfully submit that claims 57-62 are also allowable.

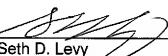
In light of the foregoing remarks, Applicant respectfully requests reconsideration and withdrawal of these rejections under 35 U.S.C. §102(b) and §103(a).

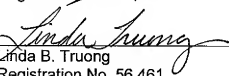
All of the claims remaining in the application are now believed to be allowable. Favorable consideration and a Notice of Allowance are earnestly solicited.

If questions remain regarding this application, the Examiner is invited to contact the undersigned at (213) 633-6800.

Respectfully submitted,

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